Remarks

The Examiner is notified that the Applicants' previous representative, Birgit E. Morris, is deceased. The Applicants' below-named representative requests recognition under 37 C.F.R. §1.34(a). A Revocation and New Power of Attorney form is expected to be filed with the United States Patent and Trademark Office in due course. In the meantime, the Examiner is requested to forward correspondence to the undersigned's attention.

The invention is directed at a method for cleaning a hemodialyzer. In general, a hemodialyzer includes a bundle of hollow permeable membrane fibers, a dialysate side inlet and outlet, and a lumen side inlet and outlet. Blood flows through the lumen side of the hemodialyzer, and various impurities in the blood pass through the hollow permeable membrane fibers into the dialysate side. After a patient uses a hemodialyzer, the hemodialyzer requires cleaning or disposal. By cleaning hemodialyzers according to the invention, it is expected that the level of cleaning and the life of the hemodialyzer can be increased compared with convention acid reagent cleaning techniques described by the specification at, for example, page 5, lines 10-21.

The method for cleaning a hemodialyzer according to the invention provides a two phase flow of a liquid cleaning solution and a gas in the lumen side of the hemodialyzer. In one technique, a liquid cleaning solution is pressurized in the dialysate side to infiltrate the liquid cleaning solution into the lumen side, and a gas is passed into the lumen side to form a two phase flow of the gas and the liquid cleaning solution in the lumen side. Alternatively, a pre-mixed mixture of a liquid cleaning solution and a gas can be applied to the lumen side of the hemodialyzer to provide a two phase flow within the lumen side.

The Prior Art-Based Rejections

The outstanding Office Action includes three prior art-based rejections. Claims 35-40, 42-53, 55, 57-67, 69, and 71-76 stand rejected under 35 U.S.C. §103(a) over European Publication No. 0 289 523 (Kopp et al.) and U.S. Patent No. 5,628,959 (Kross). Claims 41, 56, 68, and 70 stand rejected under 35 U.S.C. §103(a) over Kopp et al., Kross, and U.S. Patent No.

5,658,466 (Kawaguchi et al). Claim 54 stands rejected under 35 U.S.C. §103(a) over Kopp et al., Kross, and U.S. Patent No. 4,622,140 (Lee et al.). These rejections are traversed.

Kopp et al. are not concerned with cleaning hemodialyzers. The Examiner's attention is directed at Examples 1-10 of Kopp et al. disclosing the filtration of various suspended solids, i.e., diatomite, ferric hydroxide, bentonite, muddy water, and calcium hydroxide. Furthermore, it is pointed out that the filter according to Kopp et al. is designed so that the liquid to be recovered (the filtrate) flows from the shell side to the lumen side. That is, the feed is introduced into the shell and the external walls of the hollow fibers prevent the particulate from flowing into the lumen, and the clarified liquid is recovered from the lumen. The Examiner's attention is directed to Kopp et al. at, for example, page 7, lines 14-26, in the context of Figures 1 and 2.

It is submitted that the filter according to Kopp et al. is different from a hemodialyzer. In a hemodialyzer, the blood flows through the lumen side and impurities pass through the lumen wall into the dialysate side (or shell side). In contrast, the filter according to Kopp et al. operates by concentrating a suspension that flows through the shell side, and a clarified liquid is recovered on the lumen side. As a result of the different types of filters, the cleaning techniques described by Kopp et al. would not have suggested cleaning a hemodialyzer according to the invention.

Kopp et al. describe cleaning a filter at page 7, lines 27-50, in the context of Figures 1 and 2. Kopp et al. describe several steps. A first step can be referred to as a clarified liquid purge where the lumen outlet port 16 is closed so that the flow of clarified liquid is stopped, and pressurized clarified liquid is then introduced into the lumen through the lumen inlet port 18 to "stretch substantially all of the pores and to wash them with at least the total pore volume of clarified liquid." After the clarified liquid purge:

> "compressed gas is introduced through lumen inlet port 18, along the lumens of the fibres 12 and through the walls of the fibres into the feed suspension/concentrated steam causing violent bubbling which purges the shell of any retained species which may have built up on the outer walls of the fibres or may have been washed from within the pores of the fibres by the clarified liquid purge." See Kopp et al. at page 7, lines 30-34.

Clearly, Kopp et al. are concerned with causing the compressed gas to flow through the pores of the lumen into the shell side to dislodge particulates from the fibers into the shell side. Because one end of the lumen is closed, Kopp et al. are not creating a two phase flow through the lumen as provided by the presently claimed invention.

According to the present invention, two phase flow is provided within the lumen side for the purpose of cleaning the lumen side of the hemodialyzer. The two phase flow can be created in situ by pressurizing a liquid cleaning solution on the dialysate side so that the liquid cleaning solution infiltrates into the lumen side and combines with a gas flowing through the lumen side. Alternatively, a combination of a liquid and a gas can be applied to the lumen side to achieve two phase flow within the lumen side.

It is submitted that Kross, Kawaguchi et al., and Lee et al. fail to suggest modifying Kopp et al. to achieve the presently claimed invention.

Kross is directed at compositions and methods for sterilizing dialyzers for reuse by a dialysis patient. In particular, Kross is concerned with the use of "chlorous acid generating" compositions as sterilants. See Kross at column 3, lines 50-62. It is submitted that Kross fails to disclose providing two phase flow within the lumen side of a hemodialyzer in order to clean the hemodialyzer.

Kawaguchi et al. describe a method of sterilizing a blood dialyzer having semi-permeable polymeric dialyzing membranes by γ-ray irradiation with a high sterilization efficiency. See Kawaguchi et al. at column 2, lines 39-63. It is submitted that Kawaguchi et al fail to disclose or suggest applying a two phase flow to the lumen side of a hemodialyzer in order to clean the hemodialyzer.

Lee et al. describe "a device useful in the extracorporeal treatment of blood." See Lee et al. at column 1, line 58 through column 2, line 3. It is submitted that Lee et al. fail to disclose or suggest utilizing two phase flow in the lumen side of a hemodialyzer to clean the hemodialyzer.

In view of the above comments, it is clear that Kopp et al. are not concerned with cleaning a hemodialyzer. Furthermore, it is submitted that Kopp et al. fail to disclose or suggest utilizing a two phase flow comprising a liquid cleaning solution and a gas through a lumen side

of a hemodialyzer according to the presently claimed invention. Kross, Kawaguchi et al., and Lee et al. fail to suggest modifying Kopp et al. to achieve the presently claimed invention.

In view of the above comments, withdrawal of the prior art-based rejections is requested.

It is pointed out that new claims 94-121 would not have been obvious from Kopp et al., Kross, Kawaguchi et al., and Lee et al. for the reasons identified above.

Response to Restriction Requirement

The outstanding Office Action includes a restriction requirement. It is believed that the restriction requirement has been rendered moot by the above amendment canceling claims 24-34 and 77-93. It is submitted that new claims 94-121 are part of the invention of Group II.

Rejection under 35 U.S.C. §112

Claims 45, 46, 48, 53, 62, 63, 68, and 70 stand rejected under 35 U.S.C. §112, second paragraph. It is believed that certain grounds for this rejection have been rendered moot by the above amendment. The remaining grounds for this rejection are traversed.

Claims 46, 48, 53, 62, and 63 are amended and claim 70 is cancelled. Accordingly, the grounds for rejecting claims 46, 48, 53, 62, 63, 68, and 70 are believed to have been rendered moot by the above amendment.

Claims 45 and 62 are rejected on the grounds that it is unclear how the two phase flow is reversed. The Examiner's attention is directed to the specification at page 22, lines 3-9, where various techniques for enhancing the cleaning effectiveness of the two phase flow are discussed. It is submitted that in the context of the invention, it is the gas or air flow that creates the direction of two phase flow. This is clear from the disclosure in the application that the velocity of the gas is responsible for forming droplets of liquid in the gas stream. The Examiner's attention is directed to the specification at, for example, page 19, lines 14-21. Clearly, one skilled in the art would understand that reversing the two phase flow is caused by reversing the direction of the gas flow.

In view of the above comments, withdrawal of the rejection under 35 U.S.C. §112, second paragraph is requested.

Obviousness-type Double Patenting

Claims 35-37, 40, 41, 44-53, 56, 58, 59, 61-66, 68, 70, 71, and 73-76 stand rejected under doctrine of obviousness-type double patenting over claims 1, 7, 9, 12-17, 20, 22, 25, 28, 33, 35, and 38 of U.S. Patent No. 6,454,871 in view of Kopp et al. and U.S. Patent No. 6,027,572 (Labib et al.). In view of the above amendment introducing new claims 94-133, and in view of the above discussion of Kopp et al., the Examiner is requested to reconsider the obviousness-type double patenting rejection and determine whether or not to issue a new obviousness-type double patenting rejection.

As discussed above, Kopp et al. are not directed at cleaning a hemodialyzer whereas the presently claimed invention is directed at cleaning a hemodialyzer. Furthermore, it is pointed out that U.S. Patent No. 6,027,572 to Labib et al. is the grandparent of the above-identified patent application. Accordingly, it is unclear how the outstanding Office Action attempts to rely upon the disclosure of a patent that issued from the grandparent of the above-identified patent application in order to reject the claims of the above-identified patent application under the doctrine of obviousness-type double patenting over the claims of a patent that issued from the parent application of the above-identified patent application. If the Examiner decides to maintain this rejection under the doctrine of obviousness-type double patenting, clarification of this issue is requested.

It is believed that this application is in condition for allowance. Early notice to this effect is earnestly solicited.

Respectfully submitted,

MERCHANT & GOULD P.C.
P.O. Box 2903
Minneapolis, Minnesota 55402-0903
(612) 332-5300

Date: January 5, 2004

Dennis R. Daley
Reg. No. 34,994
DRD:sll